

## DIPLOMATE OF THE AMERICAN BOARD OF ORTHOPAEDIC SURGERY

Duane G. Messner, M.D. General Orthopaedicr

Courtney W. Brown, M.D. Traumatic, Adult & Pediatric Spine General Orthopaedics

David H. Donaldson, M.D. Traumatic, Adult & Pediatric Spine General Orthopaedics

> Thomas G. Friermood, M.D. Medical Director General Orthopaedics

Eric J. Stahl, M.D. Sports Medicine Arthroscopic & Reconstructive Surgery of the Knee & Shoulder

John L. Brugman, M.D. Traumatic, Adult & Pediatric Spine General Orthopaedics

Mark F. Mills, M.D. Total Joint Replacement, Geriatric Orthopaedics & Arthritis

Mitchell D. Seemann, M.D. Sports Medicine Arthroscopic & Reconstructive Surgery of the Knee & Shoulder

James S. Gebhard, M.D. Traumatic, Adult & Pediatric Spine General Orthopaedics

> Bharat M. Desai, M.D. Trauma, Foot & Ankle

Peter N. Lammens, M.D., FRCSC (S) Trauma & Total Joint Replacement

Douglas C. Wong, M.D. Traumatic, Adult & Pediatric Spine General Orthopaedics

> DIPLOMATE OF THE AMERICAN BOARD OF PHYSICAL MEDICINE

Ranee Shenoi, M.D. Physical Medicine and Rehabilitation, Electrodiagnosis

Administration

Linda C. Tiefel, CEO

AND REHABILITATION

 Central Office 

◆ 280.5 Kipling Street Lukewood, Colorado 80215 303-233-1223

303-233-1223 Thornton, Color 1-800-258-5250 303-452-8001 1-800-238-3230 TIIGS CHOIL COME FAX 303-233-8755

ா வெருந்து நிரு **Email: LOCbones@aol.com** நிருந்து கொணிக்கு கொணிக்கும்

♦ North Office ♦ 93.51 Grant Street Suite 490

Thornton, Colorado 80229

1010dcage power was peen made 19696 : 199 - DEC-23 -49:32

Lally to rentoten to seize furton surgery. n mode no material reforma in Carerond class considerant in e

December 13, 1999

Dockets Management Branch (HFA-305)

ATTN: Docket #97N-484S Food and Drug Administration 5630 Fishers Lane, Room 1061

Rockville, Maryland 20852

Dear Sirs:

This letter is in regards to further regulating bone allograft for use in orthopaedic surgery. It has come to my attention that there is a move to impose further regulation on allograft bone, especially in relation to spine fusion surgery.

Allograft bone has been used in spine fusions for decades successfully when used in the proper patients and proper indications. Further regulation of this material would add additional expense and is not justified, since this is a product which has been used successfully without any significant increased risk or complications over other available techniques for many years. I would therefore recommend that you not impose further regulation in the processing or use of bone allograft.

Sincerely Air Delhard

James S. Gebhard, M.D.

JSG/wld/10741

Signature stamped to avoid delay in mailing

c 172

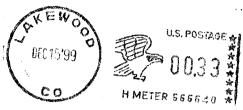
71-4845



Duane G. Messner, M.D.
Courtney W. Brown, M.D.
David H. Donaldson, M.D.
Thomas G. Friermood, M.D.
Eric J.Stahl, M.D.
John L. Brugman, M.D.
Mark F. Milis, M.D.
Mitchell D. Seemann, M.D.
James S. Gebhard, M.D.
Bharat M. Desai, M.D.
Ranee M. Shenoi, M.D.
Peter N. Lammens, M.D.
Douglas C. Wong, M.D.

1805 Kipling Street Lakewood, Colorado 80215

9351 Grant Street #490 Thornton, Colorado 80229



Dockets MNGT. Branch ATTN: Docket #97N-4848 Food + Drug administration SU30 Fishers Lane #10rel